PARTICIPANTS

Meeting Between the Institute for Clinical PET and FDA Staff on Approval Procedures for PET Drugs

February 18-19, 1999

INSTITUTE FOR CLINICAL PET

Jorge Barrio, Ph.D., Professor, Department of Molecular and Medical Pharmacology, University of California – Los Angeles

Peter S. Conti, MD, Ph.D., Associate Professor of Radiology, Clinical Pharmacy, and Biomedical Engineering, University of Southern California

Robert Ferris, Facility Manager, Mallinckrodt Medical

Ron Finn, Ph.D., Radiochemist, Memorial Sloan Kettering Cancer Center

Jennifer Keppler, Executive Director, Institute for Clinical PET

Jerry Kuhs, R.Ph., Vice President, Regulatory Affairs, PETNet

Val Lowe, M.D., Medical Director, St. Louis University PET Center

John Mather, Bioscan

Dennis Swanson, R.Ph., Director, IRB, University of Pittsburgh

98D-0266

SUP2

PARTICIPANTS

Meeting Between the Institute for Clinical PET and FDA Staff on Approval Procedures for PET Drugs

February 18-19, 1999

FOOD AND DRUG ADMINISTRATION-
CENTER FOR DRUG EVALUATION AND RESEARCH

Jane Axelrad, J.D., Associate Director for Policy

Florence Houn, M.D., MPH, Deputy Director, Office of Drug Evaluation II

David Hussong, Ph.D., Microbiologist, Office of New Drug Chemistry

Ravi Kasliwal, Ph.D., Chemistry Reviewer, Office of New Drug Chemistry

Robert K. Leedham, Jr., R.Ph., Chief, Project Management Staff, Division of Medical Imaging and Radiopharmaceutical Drug Products

Eldon Leutzinger, Ph.D., Chemistry Team Leader, Office of New Drug Chemistry

Patricia Love, M.D., Director, Division of Medical Imaging and Radiopharmaceutical Drug Products

Brian Pendleton, J.D., Regulatory Counsel, Regulatory Policy Staff

Victor Raczkowski, M.D., Deputy Director, Office of Drug Evaluation III

Tracy Roberts, M.S., Compliance Officer, Division of Manufacturing and Product Quality, Case Management and Guidance Branch, Office of Compliance

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: April 30, 2000
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
TELEPHONE NO. *(Include Area Code)*	FACSIMILE (FAX) Number *(Include Area Code)*
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):*	AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued)

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY	
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*		CODE NAME *(If any)*
DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:

(PROPOSED) INDICATION(S) FOR USE:

APPLICATION INFORMATION

APPLICATION TYPE (check one) ☐ NEW DRUG APPLICATION (21 CFR 314.50) ☐ ABBREVIATED APPLICATION (ANDA, AADA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (21 CFR part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b) (1) ☐ 505 (b) (2) ☐ 507

IF AN ANDA, OR AADA, IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug Holder of Approved Application

TYPE OF SUBMISSION (check one) ☐ ORIGINAL APPLICATION ☐ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ SUPAC SUPPLEMENT
☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

REASON FOR SUBMISSION

PROPOSED MARKETING STATUS (check one) ☐ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED _____ THIS APPLICATION IS ☐ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION

Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

This application contains the following items: *(Check all that apply)*	
	1. Index
	2. Labeling (check one) ☐ Draft Labeling ☐ Final Printed Labeling
	3. Summary (21 CFR 314.50 (c))
	4. Chemistry section
	A. Chemistry, manufacturing, and controls information (e.g. 21 CFR 314.50 (d) (1), 21 CFR 601.2)
	B. Samples (21 CFR 314.50 (e) (1), 21 CFR 601.2 (a)) (Submit only upon FDA's request)
	C. Methods validation package (e.g. 21 CFR 314.50 (e) (2) (i), 21 CFR 601.2)
	5. Nonclinical pharmacology and toxicology section (e.g. 21 CFR 314.50 (d) (2), 21 CFR 601.2)
	6. Human pharmacokinetics and bioavailability section (e.g. 21 CFR 314.50 (d) (3), 21 CFR 601.2)
	7. Clinical Microbiology (e.g. 21 CFR 314.50 (d) (4))
	8. Clinical data section (e.g. 21 CFR 314.50 (d) (5), 21 CFR 601.2)
	9. Safety update report (e.g. 21 CFR 314.50 (d) (5) (vi) (b), 21 CFR 601.2)
	10. Statistical section (e.g. 21 CFR 314.50 (d) (6), 21 CFR 601.2)
	11. Case report tabulations (e.g. 21 CFR 314.50 (f) (1), 21 CFR 601.2)
	12. Case report forms (e.g. 21 CFR 314.50 (f) (2), 21 CFR 601.2)
	13. Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))
	14. A patent certification with respect to any patent which claims the drug (21 U.S.C 355 (b) (2) or (j) (2) (A))
	15. Establishment description (21 CFR Part 600, if applicable)
	16. Debarment certification (FD&C Act 306 (k)(1))
	17. Field copy certification (21 CFR 314.50 (k) (3))
	18. User Fee Cover Sheet (Form FDA 3397)
	19. OTHER (Specify)

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR 210 and 211, 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR 201, 606, 610, 660 and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR 202.
5. Regulations on making changes in application in 21 CFR 314.70, 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80 and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been review and, to the best of my knowledge are certified to be true and accurate.

Warning: a willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
	( )

Public reporting burden for this collection of information is estimated to average 40 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS, Reports Clearance Officer
Paperwork Reduction Project (0910-0338)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Please **DO NOT RETURN** this form to this address.

★ U.S. GOVERNMENT PRINTING OFFICE: 1997-521-628

Form Approved: OMB No.: 0910-0045. Expiration Date: December 31, 1997. See OMB Statement on Reverse

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

REGISTRATION OF DRUG ESTABLISHMENT

(In accordance with Public Law 92-387)

FOR FDA USE

CONTROL NO. (1–6) | RECORD I.D. (6–11) | NO (12) = 1

PURPOSE OF FORM
- ☐ REGISTRANT
- ☐ DISTRIBUTOR ONLY
- ☐ FOREIGN COUNTRY

S (13)

REPORT DATE: MO. (14–15) DA. (16–17) YR. (18–19)

FDA VALIDATION

LINE	ESTABLISHMENT REGISTRATION NO. (20–26)	TYPE OWNER (27)	NAME TYPE (28)	REASONS FOR SUBMISSION (29–33)	BUSINESS TYPE C-HUMAN V-VETERINARY (34–37)	STATE OF INC. (38–39)	NDC LABELER CODE (40–45)	REPORTING FIRM NAME SHORT NAME (46–60)	FULL NAME (61–100)
2			M						

SITE ADDRESS

LINE	NUMBER AND STREET (101–138)	CITY (139–158)	STATE (159–160)	ZIP CODE (161–165)	FOREIGN COUNTRY (166–175)
3					

MAILING ADDRESS *(if different from site address)*

LINE	NUMBER AND STREET (176–213)	CITY (214–233)	STATE (234–235)	ZIP CODE (236–240)	FOREIGN COUNTRY (241–250)
4					

NOTICE: This report is required by law (21 C.F.R. 207.20). Failure to report can result in imprisonment for not more than one year or a fine of not more than $1,000 or both. (FD&C Act, Section 303).

PARENT COMPANY *(If any)*

LINE	NDC LABELER CODE (251–256)	SHORT NAME (257–271)	FULL NAME (272–311)	PARENT ESTAB REG NO. (312–318)
5				

NAME OF PERSON SUBMITTING DATA

AREA CODE AND PHONE NO.

COMPLETE ITEMS WITHIN HEAVILY RULED BOX FOR REGISTRATION ONLY

NAME OF OWNER, OR NAMES AND TITLES OF PARTNERS CORPORATE OFFICERS / DIRECTORS OR BOARD OF MANAGEMENT MEMBERS

	LAST NAME (27–51)	FI (52)	MI (53)	TITLE	LAST NAME (27–51)	FI (52)	MI (53)	TITLE
6								
7								
8								
9								

OTHER FIRM NAMES USED BY REPORTING ESTABLISHMENT IN DRUG HANDLING ACTIVITIES AT SITE ADDRESS

	RECORD I.D. (6–11)	NO. (12)	NT (28)	OTHER NDC LABELER CODE (40–45)	SHORT NAME (46–60)	FULL NAME (61–100)
10		1	T			
11		1	T			
12		1	T			
13		1	T			

SIGNATURE OF AUTHORIZING OFFICIAL

14 *CERTIFICATION: Signature is required if certification is being made to the registered establishments that data on products with these labeler codes are being furnished to Food and Drug Administration by private label distributor.*

SIGNATURE OF DISTRIBUTOR

TITLE

Form Approved: OMB No. 0910-0045. Expiration Date: December 31, 1997. See OMB Statement on Reverse.

DEPARTMENT OF HEALTH AND HUMANS SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DRUG PRODUCT LISTING

(In accordance with Public Law 92-387)

NAME AND ADDRESS OF FIRM

LABELING REVISON
CHANGE OF:
☐ RTE OF ADMIN ☐ INDICATION
☐ NAME / DOSE / STR / INGR
☐ OTHER *(Specify)*

FOR FDA USE

SEC	S	U	PRODUCT TRADE NAME OR CATALOG NAME	NATIONAL DRUG CODE LABELER	NATIONAL DRUG CODE PRODUCT
01					

FDA APPLICATION NO.	REPORT DATE MO	DA	YR	TYPE REPT	TYPES OF BUSINESS OTHER *(Specify)*	PRODUCT TYPE	OTHER *(Specify)*	SNDD	LEGAL STATUS	SCHED	PROF USE	PRODUCT DISCONTINUED	OTHER *(Specify)*	BASIS OF CONCENTRATION WHOLE NUMBERS	DECIMAL	UNIT

DOSAGE FORM	ROUTES OF ADMINISTRATION 1	2	3	OTH	PT	SEC	S	U	SUPL	PKG CODE	PACKAGE SIZE	PACKAGE TYPE
						03						
						03						
						03						
						03						
						03						

INITIAL MKTG DATE MO	YEAR	MOST RECENT MKTG DATE MO	YEAR	DISCONTINUED DATE MO	YEAR

NOTICE: This report is required by law (21 C.F.R. 207.20). Failure to report can result in imprisonment for not more than one year or a fine of not more than $1,000, or both (FDA&C Act, Section 303).

SEC	S	U	TYPE	PT	ESTABLISHED NAME OF PRODUCT AND / OR INGREDIENT(S) OR BIOLOGIC PROPER NAME, TEST OBJECTIVE / EQUIPMENT / REAGENT NAME, ETC.	FDA USE ONLY INGREDIENT NO.	AMOUNT WHOLE NUMBER	AMOUNT DECIMAL	UNIT
05									
05									
05									
05									
05									
05									
05									
05									
05									
05									

SEC	S	U	SITE OR FIRM ESTABLISHMENT REGISTRATION NUMBER	ACTUAL MANUFACTURING SITE OF THE ABOVE DRUG PRODUCT	STATE	FOREIGN COUNTRY	NDC LABELER CODE	SHORT NAME
07								
07								
07								